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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,195	07/31/2001	Gloria DeCarlo Massaro	17293DIV(HL)	4830
7590 02/17/2004 Carlos A. Fisher ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92623			EXAMINER SEAMAN, D MARGARET M	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/919,195

**Applicant(s)**

MASSARO ET AL.

**Examiner**

D. Margaret Seaman

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This application was filed 31 July 2001 and is a DIV of 09/548,897 (13 April 2000) which claims benefit of 60/129,213). Claims 13-28 are before the Examiner.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13-28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. As previously stated, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims do not meet the requirements for adequate written description of the claimed invention because the scope of the claims is unknown due to the structure limitations not being specifically disclosed. There is no description of the identifying characteristics for recognizing that a candidate compound antagonizes RAR $\beta$  and has specific RAR modulating activity and such antagonist is not specific to at least one other RAR receptor subtype. There are no structural characteristics of such an antagonist provided, nor is there any

indication that applicant had possession of any antagonist. Further, the claimed method required treatment of an unspecified disease. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

Applicant argues that clarity is not the job of the description requirement but the purpose is to put in the public possession of what the party claims as his own invention. However, if the specification is not clear as to what is the scope of the instant invention, then the invention is not adequately described. The specification does not have adequate written description of what compound do or do not fit within the bounds of the instant claim 13. The only compounds that fit within the bounds of the instant claim 13 are the compounds/methods of the US Patent #6,303,648. The instant specification does not have written description as to how to make compounds that fit within the instant parameters outside the compounds of the parent patent.

3. Claims 13-28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated previously, the claimed invention is drawn to compositions that have RAR $\beta$  antagonist having specific RAR modulating activity and a method of treating using such compositions. However, the only compounds that are enabled by the instant specification have already been patented. No other

compounds have been suggested or enabled by the instant specification. It is not seen where the instant specification enables the ordinary artisan to make or use the instant invention without undue experimentation.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to any and all known and unknown compounds that have RAR antagonist having specific RAR modulating activity.

3) The state of the prior art: The prior art has specific compounds that have utility as RAR  $\alpha$ ,  $\beta$ , and  $\gamma$  antagonist activities either specifically or generally to the RAR  $\alpha$ ,  $\beta$ , and  $\gamma$ . However, the prior art starts with a compound and determines that the compound has certain activity. The prior art does not specify an activity and then searches any and all known and unknown compounds to find one or more that fit the activity.

5) The level of predictability in the art: The level of predictability in the art is low due to the hit or miss style of determining first the compound and then testing the compound

to see if it has the required activity. There is no core of compounds from which to base the predictability from, only an activity that all compounds known and unknown may or may not possess.

6) The amount of direction provided by the inventor: The inventor provides no direction beyond compounds already known (and patented) that have the RAR antagonist activity. There is no guidance as to where to go from the specific compound disclosed on page 16 of the instant specification. The specification provides only a method of testing, not a direction of which to test.

7) The existence of working examples: There is one compound shown on page 16 of the specification. There are no other working examples.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation needed to make/use the instant invention is unexpected. The test available only gives the test to which a compound can be shown to either have or not have the needed activity. The test does not provide a direction to which the ordinary skilled artisan should proceed other than any and all known and unknown compounds.

Taking the above factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make/use the instant invention without undue experimentation.

The specification does not provide any guidance with exception to the compounds of the parent patent, with respect to any working examples. One skilled in

the art would first have to determine the activity of the receptor in order to develop the claimed invention. If the ordinary artisan doesn't know the structure of what compound meets the particulars of the instant claims, then the ordinary artisan doesn't know how to make the compounds that fulfill the instant claims. Furthermore, no information is presented as to how the undisclosed antagonist compound would have been administered to treat an unspecified disease. Thus, the skilled artisan would not have been able to practice the steps required by the claimed invention.

Applicant argues that the Wands factors are not mandatory and the only relevance is to the facts. The Wands factors illustrate the facts. Due to this, they are relevant to the instant argument. Taking all of the above facts into consideration, it is not seen where the instant specification enables the ordinary artisan to make and use the instant invention.

#### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 13-28 under 35 U.S.C. 102(b) as being anticipated by Ghaffari, Cong, Xu, Wu, Cao, Song and Yu, is upheld.

As stated previously, Ghaffari discloses compounds that RAR modulation that affects the lung. Cong discloses RAR modulation in its role in the development of the lung. Xu discloses modulation of RAR for lung problems. Wu discloses RAR modulation in lung problems. Cao discloses RAR modulation in the lung tissue. Song discloses RAR modulation in the lung tissue. Yu teaches RAR modulation and its link to the lungs. These all teach RAR modulation and lung tissues. These compounds would inherently encompass the instantly claimed invention.

Applicant argues that the instant claims are not drawn to lung tissue. However, the instant claims (13-20) are drawn to the treatment or prevention of alveolar destruction. The alveolar is in lung tissues. The instant claims (claims 21-28) are drawn to the increase of the gas-exchange surface area of mammalian lungs. This occurs in lung tissues. The cited prior art deals with RAR modulation that affects lung tissues. All of these inherently encompass the instant claims. The prior art teaches a method for treating the same final conditions as is instantly claimed. Due to this, the prior art inherently must have the same activities as instantly claimed. The rejection is upheld.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).




A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms